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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/863,035	05/22/2001	Stanislaw R. Burzynski	10379.0047.DVUS00	1265

7590

12/17/2003

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EXAMINER
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COOK, REBECCA

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 12/17/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/863,035

Applicant(s)

BURZYNSKI, STANISLAW R.

Examiner

Rebecca Cook

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 28-30, 48-53 are is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28-30, 48-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

In view of the amendment to the claims, the earlier rejection under 35 USC 112, paragraph one is withdrawn.

In view of applicant's arguments the earlier rejection under 35 USC 103(a) to Burzynski is withdrawn.

### **Claim Objection**

Claim 53 is objected to as not further limiting claim 28. It recites the limitation "4:1 ratio by weight." However, claim 28 recites said limitation.

### ***Claim Rejections - 35 USC § 112***

Claims 28-30 and 48-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 28 the phrase "carcinoma of an unknown primary" is confusing. The phrase would be more clear if it recited "carcinoma of an unknown primary source" if this is the intent of the applicant. Furthermore, it is not clear that the patient needs the recited treatment. Amending the claim to recite "A method of treating a neoplastic disease in a patient in need thereof" will overcome this rejection.

In claim 48 the intent of the phrase "The method of composition of claim 28 wherein in the compound" is not clear. Amending the phrase to recite "The method of claim 28, wherein in the compound" will overcome this rejection.

In claim 49 it appears that when the compound of Formula IV or of Formula I or of Formula III is a salt more than one salt is required. Amending the claim to recite "or a pharmaceutically acceptable salt" will overcome this rejection.

In claims 51 and 52 the phrase "pharmaceutically acceptable salts" makes it appear that more than one salt is required. Amending the phrase to recite "or a pharmaceutically acceptable salt" will overcome this rejection.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 28—30, 48-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adam as disclosed by the applicant (page 5, third complete paragraph) of the specification.

Applicant discloses that Adam et al teach using A10 (compound III) and AS2-1 (compound IV) to treat cancer.

The instant independent claim differs over Adam et al in reciting the use of the compound of Formula III and the compound of Formula IV together, a ratio of the compound of Formula IV and the compound of III of 4:1 and that the total combined concentration of the compound of Formula IV and the compound of Formula III is from 70 mg/ml to 150/mg/ml. Dependent claims recite specific dosages, rates of infusion and combined concentration of compounds.

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However, in the absence of a showing of unexpected results no unobviousness is seen in combining the compound of Formula III and the compound of Formula IV together, since each is taught to be useful to treat cancer. Furthermore, once the usefulness of a composition is taught, it is within the skill of the artisan to determine the optimum dosages, rates of infusion and combined concentration of compounds.

### ***Conclusion***

Applicant is requested to provide a fuller citation for Adam so that it may be ordered, or the printed publication in order to complete the record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (703) 308-4724. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



REBECCA COOK  
PRIMARY EXAMINER  
GROUP 1200/614

December 15, 2003